

## **2. RESPONSE/REMARKS**

### **2.1 STATUS OF THE CLAIMS**

*Claims 1-12 and 21-40 were pending at the time of the Action.*

*Claims 22-23, 29, and 35-37 have been amended herein.*

*Claims 1-12 and 21-40 remain pending in the application.*

Applicants respectfully request reconsideration of the remarks herein, removal of all outstanding claim objections and rejections, and allowance of all pending claims.

### **2.2 SUPPORT FOR THE CLAIMS**

Support for the pending claims can be found throughout the original claims, specification and figures as filed. It will be understood that no new matter is included within any of the amended claims.

### **2.3 REJECTION OF CLAIM 29 UNDER 35 U. S. C. §101 IS OVERCOME.**

*The Action at page 3 rejected claim 29 under 35 U. S. C. § 101, allegedly as being directed to non-statutory subject matter.*

The Office takes the position that claim 29 reads on a human being that comprises the cell. Applicants respectfully traverse. However, in the interest of advancing claims of particular interest and commercial relevance, and to prevent a protracted examination, Applicants have amended claim 29 to recite “An isolated mammalian host cell...” which is indicative of Applicants recognition that they do not intend for the claim to be construed as including within its scope whole human beings.

Applicants respectfully request that the rejection be withdrawn.

**2.4 OBJECTION TO CLAIM 37 IS OVERCOME.**

*The Action at page 12 objected to claim 37 as allegedly because of a typographical error.* Applicants appreciate the attention of the Examiner in pointing out the error, and have amended the claim to correct the inadvertent error.

Applicants respectfully request therefore, that the rejection be withdrawn.

**2.5 OBJECTIONS TO CLAIMS 31 AND 32 ARE IMPROPER.**

*The Action at page 12 objected to claims 31 and 32 as allegedly because “it is noted that the ‘instructions’ are a physical component of the claimed kit, but are not patentable because they are not functionally related to the instant polypeptide.”.*

Applicants respectfully traverse, and note for the record that one component of a kit need not be “functionally related to the instant polypeptide” in order to be patentable. In fact, the kit as presently claimed does not even comprise a polypeptide! The composition of claim 1 comprises a recombinant adeno-associated viral (rAAV) vector that contains a nucleic acid segment that encodes a pro-opiomelanocortin polypeptide. The composition itself does not comprise a polypeptide. As such, the present rejection is in error.

Furthermore, it is widely accepted in the present art unit that “kit” claims, which often address commercial packaged formulations of the claimed novel and non-obvious compositions, and the Applicants are mystified why the Examiner is of the opinion that a claim directed to such a composition and instructions for its use is not statutory because “the instructions are not functionally related to the instant polypeptide.”

As the rejection is improper, Applicants respectfully request that it now be withdrawn.

**2.6 REJECTION OF CLAIMS 1-12, 21-30 UNDER 35 U. S. C. §112, 1<sup>ST</sup> PAR., IS OVERCOME.**

*The Action at page 3 rejected claims 1-12, 21-30 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph, allegedly because the Specification “while being enabling for administration of rAAV-POMC compositions to the hypothalamic arcuate nucleus” of a mammal “does not reasonably provide enablement for other methods of delivery (for example, intramuscular).”*

Applicants respectfully traverse, and incorporate herein by reference their arguments previously advanced in their earlier response to non-final Action regarding this rejection. Applicants note for the record that the novel and non-obvious rAAV-POMC vector compositions are fully enabled by the present Specification, and that Applicants have demonstrated *in vivo* success in using these compositions in an accepted animal model (rat) of disease.

Applicants understand that the Examiner, while acknowledging that methods of *directly providing* rAAV-POMC vector constructs of the invention to brain tissues of an affected mammal are clearly enabled by the specification, is of the position that systemic or localized injection (*e.g.*, intramuscular) of the viral constructs to *other* sites in the body, for example, by administering the compositions intravenously, systemically, or locally to sites in the body *other than* neural tissue or the brain is “unpredictable” or would require “undue experimentation” to practice the claimed methods.

Applicants respectfully traverse, and are of the position that the administration of the claimed rAAV-POMC constructs in no way need necessarily be directly administered to neural tissue or to the brain in order to affect a beneficial therapeutic response.

However, mindful of patent term, economic costs associated with a protracted examination, and solely in order to advance certain claims of particular scope to rapid allowance

in view of commercialization and other market-based influences, and without acquiescing in any way to the propriety of the present scope rejection, Applicants have provided the present amendment to particularly address certain aspects of concern raised by the Examiner, and to facilitate a ready allowance of the pending claims.

To that end, Applicants believe that the present submission fully addresses any concerns the Examiner may have, and that enablement for presently-claimed embodiments, which are of particular economic significance to Applicants is fully present in the original specification and claims as presented, and are entitled to the full priority claim of the present application. Applicants have amended claim 22 to recite rAAV-POMC compositions formulated for intracerebroventricular administration to a mammalian brain, and in claim 23, claim language has been clarified regarding direct administration of the rAAV-POMC compositions particularly to the arcuate nucleus of a human hypothalamus.

Therefore, Applicants respectfully request that the Examiner withdraw the rejection in view of the present claims, and explicitly note for their record their right to re-file and pursue claims towards additional embodiments and claims of differing scope to the present embodiments in suitable continuing and/or divisional application(s) claiming priority to the present application at any such time during prosecution of the present application.

**2.7 REJECTION OF CLAIMS 35 AND 36 UNDER 35 U. S. C. §112, 1<sup>ST</sup> PAR., IS OVERCOME.**

*The Action at page 13 rejects claims 35-36 under 35 U. S. C. § 112, 1<sup>st</sup> paragraph, allegedly because the Specification "while being enabling for administration of rAAV-POMC compositions to the hypothalamic arcuate nucleus of a mammalian brain, it does not reasonably provide enablement for other methods of delivery (for example intramuscular)."*

Applicants respectfully traverse. However, in the interest of advancing claims of particular interest and commercial relevance to allowance, Applicants have amended claims 35

and 36 to encompass rAAV-POMC compositions formulated for, and directly delivered to, the intracerebroventricular region of a mammalian, and particularly human, brain.

As such, Applicants respectfully request that the rejection be withdrawn.

## **2.8 REJECTION OF CLAIMS UNDER 35 U. S. C. § 103(A) IS MOOT.**

Applicants noted in their previous response that the Paterna reference is only available as prior art under 35 U. S. C. § 102(A), and not 35 U. S. C. § 102(B) as it was published less than a year before the priority date of the instant application. The Examiner acknowledges this in his comments on page 7 of the present Action, but seems not to understand the significance of this point, and asks Applicant “to explain why such a distinction between 102(a) and 102(b) is necessary for 103 purposes.”

Applicants are happy to summarize for the Examiner the relevant aspects of the Law:

For a reference to be available under Section 103(a), it must be citable under one of the provisions of Section 102(b). As noted in Applicants’ previous response, since the Paterna reference was published less than a year before Applicants’ priority date, it is properly available as prior art only under Section 102(a), and NOT under Section 102(b).

Furthermore, a reference available under Section 102(a) can be removed as prior art by submission of a suitable antedating affidavit under 37 C. F. R. § 1.131 demonstrating invention in the United States prior to the date of publication of the Section 102(a) reference.

Thus, a submission of an antedating affidavit under 37 C. F. R. § 1.131 would render the Paterna reference unavailable as prior art under Section 102(a), which would also render the reference unavailable for citation under any provision of Section 103(a).

Moreover, since Bognasco was *also* published less than a year before the priority date of the instant application, it, too, is only available for citation under Section 102(a) (and not Section 102(b)). Therefore, an antedating affidavit by the Applicants demonstrating invention in the U.S. prior to the publication of the Bognasco reference, would also be effective to render the Bognasco reference citable under neither Section 102 OR Section 103.

To that end, Applicants have submitted herewith a Statutory Declaration of inventors Scarpace and Li, demonstrating invention in the United States PRIOR TO the publication dates of both Paterna *and* Bognasco, and as such, both references are removed as prior art, and hence, they are unavailable to cite under Section 103(a) either alone, or in combination with any other reference(s). Simply put, neither Paterna nor Bognasco is available as prior art, and hence, any rejection made over them must be withdrawn.

In summary therefore, in view of the antedating affidavit submitted herewith, Applicants now respectfully submit that each of the rejections under 35 U. S. C. § 103(a) is improper, as each cite either Paterna and/or Bognasco in combination with one or more references. Because neither Paterna nor Bognasco is available as prior art, each rejection over them must be withdrawn as impermissible.

## **2.9 A STATUTORY DECLARATION UNDER 37 C. F. R. § 1.131 IS PROVIDED.**

Without acquiescing in anyway to the propriety of the obviousness rejections advanced in view of Paterna and/or Bognasco, and without agreeing in any manner with the Office's characterization of what the Paterna and/or Bognasco references do or do not "teach or suggest," or whether or not any aspects of the present invention is potentially "anticipated" by either of the cited references, Applicants respectfully note for the record that these two references were

published less than a year before the April 11, 2003 priority date claimed by the present application, and as such, are subject to removal as prior art pursuant to a submission under 37 C.F.R. § 1.131.

Attached hereto as Exhibit 1, Applicants have submitted a Statutory Declaration Under 37 C.F.R. § 1.131 of inventors Scarpace and Li effectively antedating both the Paterna and Bognasco references by demonstrating Applicants' invention of the claimed subject matter in the United States prior to the publication dates of both the October 9, 2002 Paterna reference and the November 2002 Bagnasco reference.

The Statutory Declaration submitted herewith provides documentary evidence attached thereto in Exhibits A-H that clearly demonstrate (a) that the inventors conceived of the claimed invention in the United States at a time prior to the publication of both the Paterna and the Bognasco references; (b) that the inventors acted diligently in both the conception and reduction to practice of the invention in the United States from a time prior to the October 9, 2002 publication of Paterna (and hence also prior to the November 2002 publication of Bognasco; (c) that the Assignee of Record and its patent counsel acted diligently to prepare and file a provisional patent application for the invention; (d) that the Assignee of Record and its patent counsel further acted diligently to convert the provisional application to the present utility application; and (e) subsequent to a time prior to the publication of the Paterna and Bognasco references, the inventors have diligently continued in their research efforts involving various embodiments of the invention as described in the present, and in the prior application, from which the present application properly claims priority.

**2.10 THE VARIOUS REJECTIONS OF CLAIMS UNDER 35 U. S. C. §103 ARE OVERCOME.**

*The Action at page 6 rejected claims 1-7, 11, 12, 21, 24, and 26-30 under 35 U. S. C. §103(a), allegedly as being legally obvious in view of Pritchard et al., (J. Endocrinol., 172:411-42, 2003)(hereinafter, "Pritchard") when taken together with Paterna et al., (Methods, 28:208-218, 2002) (hereinafter "Paterna").*

Applicants respectfully traverse, and note that Paterna has been removed as prior art by the inventors' statutory antedating affidavit under 37 C.F.R. § 1.131 submitted herewith. In view of this declaration, Paterna is no longer available as prior art under 35 U. S. C. § 102 , and as a result, any combination of references including Paterna is now improper under 35 U. S. C. § 103. Because this rejection is made over the combination of Paterna and Pritchard, it is now improper, and must be withdrawn.

*The Action at page 9 rejected claims 1-9, 21, 26 and 27 under 35 U. S. C. §103(a), allegedly as being legally obvious in view of Pritchard and Paterna further in view of Lasic (Tibtech, 16:307-321, 1998) (hereinafter "Lasic").*

Applicants respectfully traverse, and as noted above, have removed Paterna as prior art by submission of the enclosed antedating affidavit under 37 C.F.R. § 1.131. In view of this declaration, Paterna is no longer available as prior art under 35 U. S. C. § 102 , and as a result, any combination of references including Paterna is now improper under 35 U. S. C. § 103. Because this rejection is made over the combination of Paterna and Pritchard in further view of Lasic, it is now improper, and must be withdrawn.

*The Action at page 10 rejected claims 1-7, 11, 12, 21-24, 26-28 and 30 under 35 U. S. C. §103(a), allegedly as being legally obvious in view of Pritchard and Paterna further in view of Keir et al. (Exp. Neurol. 160:313-316, 1999) (hereinafter "Keir").*

Again, Applicants respectfully traverse. As noted above, the enclosed antedating affidavit under 37 C.F.R. § 1.131 has removed Paterna as prior art under 35 U. S. C. § 102 , and as a result, any combination of references including Paterna is also impermissible under 35 U. S. C. § 103. Because the present rejection is made over the combination of Paterna and Pritchard further in view of Keir, it is now improper, and must be withdrawn.



*The Action at page 11 rejected claims 1-8, 11, 12, 21-24, 26-28 and 30 under 35 U. S. C. §103(a), allegedly as being legally obvious in view of Pritchard and Paterna further in view of U.S. Patent 6,156,303 to Russell et al. (hereinafter “Russell”).*

For the same reasons stated above, Applicants again respectfully traverse. Because the present rejection is made over the combination of Paterna and Pritchard further in view of Russell, and the Paterna reference is no longer available for citing under 35 U. S. C. § 103, this rejection over the combination of references is also now improper, and respectfully must be withdrawn.

*The Action at page 13 rejected new claims 31-40 under 35 U. S. C. §103(a), allegedly as being legally obvious in view of Pritchard et al., (J. Endocrinol., 172:411-42, 2003)(hereinafter, “Pritchard”) when taken together with Paterna et al., (Methods, 28:208-218, 2002) (hereinafter “Paterna”).*

Again, Applicants respectfully traverse; noting that Paterna is no longer available for citing under 35 U. S. C. § 103, the rejection of claims 31-40 over the combination of Pritchard and Paterna is also now improper, and therefore, Applicants respectfully request that the rejection be withdrawn.

As such, Applicants respectfully request that each of the Section 103(a) rejections now be withdrawn.

## **2.11 REQUEST FOR CONTINUED EXAMINATION (RCE)**

The present RCE is filed within the statutory six month period after the Final Action and is timely in light of the enclosed request for extension of time and fees.

## **2.12 REQUEST FOR EXAMINER INTERVIEW**

Pursuant to M. P. E. P. § 713.01 and 37 C. F. R. § 1.133, Applicants hereby request an interview with Applicants’ undersigned representative in order to facilitate an expeditious conclusion of prosecution on the merits in the present application, and to permit expedited

allowance and issuance of the pending claims prior to the issuance of a first action on the merits in the Request for Continued Examination filed herewith.

Consistent with M. P. E. P. §§ 408 and 713.09, Applicants request that the Examiner contact the undersigned representative within the next 30 days to arrange a telephonic Examiner Interview at a mutually convenient time to discuss favorable disposition of the case and the resolution of the issues of record as soon as he has had the opportunity to review and consider the present paper, and before issuance of a first action on the merits in the RCE.

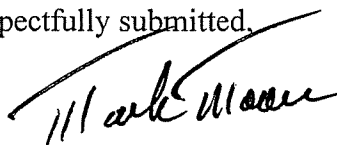
## **2.13 CONCLUSION**

It is respectfully submitted that all claims are fully enabled by the Specification, and that all claims are definite, and free of the prior art. Applicants believe that the claims are acceptable under all sections of the Statutes and are now in conditions for ready allowance, and that all of the concerns of the Examiner have been resolved. Applicants earnestly solicit concurrence by the Examiner and the issuance of a Notice of Allowance in the case with all due speed.

Applicants note for the record their explicit right to re-file claims to one or more aspects of the invention as originally claimed in one or more continuing application(s) retaining the priority claim from the present and parent cases.

Should the Examiner have any questions, a telephone call to the undersigned Applicants' representative would be appreciated, particularly in advance of any subsequent action on the merits.

Respectfully submitted,



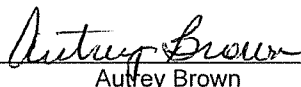
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